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10/588,159

08/01/2006

Jong Hoon Hahn

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

EDWARDS, LYDIA E

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

01/27/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
USPTO@SUGHRUE.COM

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/588,159 | <b>Applicant(s)</b><br>HAHN ET AL. |  |
|                              | <b>Examiner</b><br>LYDIA EDWARDS     | <b>Art Unit</b><br>1797            |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/1/2006, 11/20/2006, 7/16/2007, 12/30/2009.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 10-12, 17-19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Corbett et al. (WO03/016558).

Regarding Claims 1 and 3, Corbett et al ('558) teaches a continuous flow thermal device comprising a cylindrical block (1:3) having two or more segments (2:11, 12, 13) each of which can be heated to a predetermined temperature. A conduit (1:1) is provided for holding a sample physically disposed in thermal contact with the block (1:3) and exits the device by conduit (1:4) (Page 10, line 30-Page 11, line 24). Corbett et al. does not disclose the use of two heating blocks. However he does disclose wherein the cylindrical block (1:3) has two or more segments, preferably three, each of which can be heated to a predetermined temperature. The examiner interprets the segments of Corbett et al. to be the same as the claimed at least two solid heating blocks.

Regarding Claim 17, Corbett et al ('558) teaches a method of performing a continuous flow nucleic acid amplification comprising injecting at least one polymerase chain reaction mixture into the first open end of the conduit (1:1); and controlling the flow rate of the

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polymerase chain reaction mixture at an appropriate speed and collecting a polymerase chain reaction product discharged from the second open end (1:4) (Page 8, line 30-Page, line 9; Page 10, lines 30-Page 11, line 10; Page 12, lines 6-18).

Regarding Claim 18, Corbett et al ('558) teaches wherein the capillary tube contacts sequentially or repetitively the heating blocks each of whose temperature is set at 95-100°C, 45-65°C, and 65-72°C (Page 11, lines 11-17).

Regarding Claims 10-12 and 19, Corbett et al ('558) teaches wherein the capillary tube is wound on the outer surface of the heating blocks; wherein the capillary tube is fit into a helical groove formed on the outer surface of the heating blocks; wherein the capillary tube is wound approximately 35-60 turns (Page 5, lines 15-20; Figures 1, 2a, 2b, and 4).

Regarding Claim 23, Corbett et al ('558) teaches wherein the polymerase chain reaction mixture moves from the first open end to the second open end by a pump (Page 11, line 25-Page 12, line 5).

Claims 1-4, 8-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Holcroft (WO98/16313).

Regarding Claims 1 and 3, Holcroft ('313) teaches heating apparatus for repeated thermal cycling of a sample comprising a cylindrical block (1:9) having two or more segments (1:10) each of which can be heated to a predetermined temperature and separated by thermally insulators (1:11). A tube (1:8) is provided for holding a sample physically disposed in thermal

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contact with the block (1:9). Movement of the sample within the tube means (1:8) causes sequential and cyclic exposure of the sample to heated segments (1:10) of the block (1:9) and thereby to different temperature cycles (page 1, lines 1-2; Page 2, lines 6-18; Figure 1). Holcroft also discloses wherein multiple pairs of heaters can be used to process multiple samples, using different temperature profiles (Page 3, lines 10-15; Figure 4).

Regarding Claims 2, 13 and 16, Holcroft ('313) teaches heating apparatus for repeated thermal cycling of a sample comprising a cylindrical block (1:9) having two or more segments (1:10) each of which can be heated to a predetermined temperature and separated by thermally insulators (1:11). A tube (1:8) is provided for holding a sample physically disposed in thermal contact with the block (1:9). Movement of the sample within the tube means (1:8) causes sequential and cyclic exposure of the sample to heated segments (1:10) of the block (1:9) and thereby to different temperature cycles (page 1, lines 1-2; Page 2, lines 6-18; Figure 1). Holcroft also discloses wherein multiple pairs of heaters can be used to process multiple samples, using different temperature profiles (Page 3, lines 10-15; Figure 4). Holcroft does not disclose wherein multiple heating blocks are separated by an insulating block. However, he does disclose wherein the heating block (1:9) comprises two or more, but ideally three, individual segment (1:10) separated by thermally insulators (1:11). Furthermore, each segment (1:10) is heated electrically and held at the appropriate temperature (Page 2, lines 6-18). The examiner interprets the segments of Corbett et al. to be the same as the claimed at least two solid heating blocks.

Regarding Claim 4, Holcroft ('313) does not explicitly state wherein the heating blocks are controlled at different temperatures by a heater and a temperature sensor. However, he does

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state that each segment (1:10) is heated electrically and held at the appropriate temperature (Page 2, lines 8-11). Therefore, controlling the temperature of the heating block by a heater and a temperature sensor would be an inherent property of the device of Holcroft given the need to heat and maintain the temperatures of the various heating blocks and the respective segments.

Furthermore, with respect to the intended use limitations, the device disclosed by Holcroft is structurally the same as the instantly claimed and is capable of providing the operating conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Regarding claims 8-9, the claims fail to further limit the structure of the device as claimed in claim 1 or 2.

Regarding Claims 10-12, Holcroft ('313) teaches wherein the capillary tube is wound on the outer surface of the heating blocks; wherein the capillary tube is fit into a helical groove formed on the outer surface of the heating blocks; wherein the capillary tube is wound approximately 30 turns (Page 2, lines 6-18; Figure 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holcroft (WO98/16313) in view of Zaun et al. (US 5415839).

Regarding Claims 5, Holcroft ('313) does not disclose the materials in which the device is composed.

Zaun et al. ('839) discloses that it was known in the art at the time the invention was made to provide a heating block made of aluminum (Col 36, lines 64-66).



Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select an appropriate material to manufacture the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holcroft (WO98/16313) in view of Blackburn (US 2003/0190608).

Regarding Claims 6, Holcroft ('313) does not disclose the materials in which the device is composed.

Blackburn ('313) discloses that it was known in the art at the time the invention was made to provide thermal insulating material made of glass, silicon, plastic or ceramic (Paragraph 321).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select an appropriate material to manufacture the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holcroft (WO98/16313) in view of Zou et al (US 20030008286).

Regarding Claims 7, Holcroft ('313) does not disclose the materials in which the device is composed.

Zou et al. ('286) discloses that it was known in the art at the time the invention was made to provide a capillary tube made of plastic, silicon and glass (Paragraph 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select an appropriate material to manufacture the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 17-19 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holcroft (WO98/16313) as disclosed above in claims 1 and 2, further in view of Corbett et al. (US 5270183).

The rejection of claims 1 and 2 above are relied upon.

Regarding Claims 17 and 23-25, Holcroft is silent with the regards to a method for performing a nucleic acid amplification, therefore it would have been necessary and thus obvious to look to prior art for a conventional method of performing a nucleic acid amplification.

Corbett et al. ('183) teaches a reaction mixture comprising the sample containing the DNA sequence(s) to be amplified, thermostable DNA polymerase (or an enzymatically active fragment thereof or an enzymatically active derivative thereof or a reverse transcriptase),

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oligonucleotide primers, the four deoxyribonucleotide triphosphates and other desirable components in a small volume, approximately 5-20 microliters, is injected by means [24] into tube [12] via inlet port [16]. Provided at one end of tube [12] is pump means [14]. The pump means maintains the flow of liquid along tube [12] in the direction shown by arrows 15. Provided on tube [12] is inlet port [16] through which reaction mixture is injected by means [24]. The carrier fluid [46] carries the reaction mixture [44] through temperature zone [18], in which DNA strands are denatured, to temperature zone [20], where annealing of the oligonucleotide primers takes place, to temperature zone [22], where synthesis of new DNA stands takes place, then back to temperature zone [18]. A small volume of purging solution [48] is injected after reaction mixture 44 by means 26 into tube [12] via inlet port [16]. The next reaction mixture 42 is then injected by means [24] into tube [12] via inlet port [16]. These processes can be repeated continuously at intervals of a few seconds, depending on the flow rate along tube [12] (Col 7, line 58-Col 8, line 68).

Corbett also teaches wherein there are two or three, and most preferably two, zones of differing temperature. Where there are three zones of differing temperatures it is preferred that one zone is at about 94 degrees Celsius, one zone at about 60 degrees Celsius, and one zone at about 73 degrees Celsius. It is preferred that the time taken for the fluid carrier stream containing the reaction mixture to pass through these three zones is about 20 seconds, about 10 seconds and about 2 minutes, respectively. However, the most suitable temperatures of the three differing zones and the most suitable time taken for the fluid carrier stream containing the reaction mixture to pass through these three zones is dependent on the enzyme used for DNA synthesis,

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the sequence composition of the oligonucleotide primers and the sequence composition of the defined target DNA sequence(s) in the sample (Col 4, line 60-Col 5, line 8).

Corbett teaches that it is known in the art at the time the invention was made to modify device of Holcroft to include a method for performing a nucleic acid amplification motivated by the expectation of successfully practicing the invention of Holcroft.

Regarding Claim 19 Holcroft ('313), teaches wherein the capillary tube repetitively contacts the heating block approximately 30 turns (Page 2, lines 6-18; Figure 1).

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holcroft (WO98/16313) in view of Corbett et al. (US 5270183) as disclosed above in claim 17, further in view of Sorge (US 6548250).

Regarding Claims 20-21, Holcroft et al. ('313) and Corbett ('183) are silent towards the composition of the polymerase chain reaction mixture.

Sorge discloses that it was known in the art at the time the invention was made to use a PCR mixture as claimed in order to test the presence of a target (Col 51, lines 16-42).

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to compose a specified reaction mixture for any number of reactions, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holcroft (WO98/16313) as disclosed above in claims 1 and 2, further in view of Corbett et al. (WO 03/16558).

The rejection of claims 1 and 2 above are relied upon.

Regarding Claims 14 and 15 Holcroft does not disclose wherein the device of claim 1 or 2, detects the degree of the reaction in real-time.

Corbett et al. ('558) disclose a continuous flow thermal device further comprising: a fluorescence-inducing apparatus having a light source for inducing fluorescence, a unit for detecting fluorescence, and an optical system for collecting emitted fluorescence to the unit for detecting fluorescence after light irradiation to the capillary tube; and a scanning unit changing the relative positions of the fluorescence- inducing apparatus and the capillary tube (Page 9, lines 16-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Holcroft with the detection means of Corbett to track and monitor the reaction(s) in the conduit.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holcroft (WO98/16313) in view of Corbett et al. (US 5270183) as disclosed above in claim 17, further in view of Corbett et al. (WO 03/16558).

Regarding Claim 22, Holcroft does not disclose wherein the polymerase chain reaction mixture further comprises at least one intercalating dye that emits fluorescence.

Corbett et al. ('558) disclose wherein the polymerase chain reaction mixture further comprises at least one intercalating dye that emits fluorescence (Page 9, lines 19-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Holcroft with the dye of Corbett to employ a detection means to allow for tracking and monitoring the reaction(s) in the conduit.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYDIA EDWARDS/  
Examiner  
Art Unit 1797

LE

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797